

**Summary of the
Environmental Laboratory Advisory Board Teleconference
April 16, 1998**

The Environmental Laboratory Advisory Board convened by teleconference on Thursday, April 16, 1998 at 2:00 p.m. Eastern Time. The meeting was led by its co-chairs, Dr. Wilson Hershey of Lancaster Laboratories and Ms. Ramona Trovato, EPA. A list of action items is provided in Attachment A and a list of participants is provided in Attachment B.

Welcome and Introduction

Dr. Hershey introduced Mr. Jerry Parr, a newly appointed member who is filling the unexpired term of Ms. Linda Christenson. Mr. Parr is representing the Global Institute of Environmental Scientists.

Discussion of the GLP Subcommittee Final Report

Dr. Hershey pointed out that based on the subcommittee report, letter and e-mail responses from the regulated community shows that they are opposed to a GLP accreditation as part of NELAC. He opened the meeting to the committee for comment. Following comment from a member of the GLP community that ELAB should not attempt to modify a report that was prepared by experts in the field, it was the opinion of several of the committee members that ELAB should endorse the GLP subcommittee's report without change and pass it onto the EPA. Ms. Jeanne Mourrain pointed out that the Office of General Counsel had recently reminded all Designated Federal Officials that, "These working groups cannot give advice and recommendation directly to EPA. They must work through the parent committee. Moreover, EPA staff may not use the advice and recommendations prior to its being forwarded to EPA as a recommendation of the chartered advisory committee. EPA encourages workgroups to allow interested members of the public to attend workgroup meetings when practicable."

Dr. Hershey suggested that in a cover letter editorial comments should be made but not alter the report. He felt it might be beneficial to point out how NELAC could be adapted to serve GLP laboratories.

Ms. Trovato gave a brief history of NELAC and how the issue of the feasibility of the GLP's coming under NELAC came into consideration. She stated that in the beginning the concept was to have all laboratories under one umbrella. Ms. Mourrain noted that a parallel process for the GLP's separate from the NELAC standards was envisioned.

Mr. Parr suggested, that in the cover letter to EPA, ELAB agree that the GLP report represents the views of the subcommittee but the ELAB has some concerns and address those concerns in the letter. Ms. Mourrain noted, in reference to the sixth bullet on page 3 of the report, "Failure of NELAP to use the existing rule-making process to introduce and implement change to the current program," that there is nothing to restrict the Agency in continuing to use the regulatory process

even if they develop revised standards through NELAC.

The committee reviewed the set of concluding recommendations and made the following changes:

- 1) The committee agreed with the recommendation to continue to disengage the GLP issue and FIFRA/TSCA programs from NELAP activity and timeline until a decision is reached by EPA.
- 2) Focus immediately on implementing Option 1. Should the modification in concert with harmonization efforts with the OECD GLP principles still not address the perceived deficiencies of the OECA compliance monitoring program, thereafter, consider on a longer-term scale, the value to be added by implementing other options identified in this report. The recognition of the sponsor's current auditing program is intended to be an adjunct to the EPA's compliance monitoring inspection program not to supplant independent audits by EPA or its designee.

After much discussion, it was agreed that the subcommittee chair, Mr. Wynn John, would make the following changes to the report:

On page 3, the paragraph beginning with **Position Relative to NELAP:** the word "unanimous" in the third line would be changed to "overwhelmingly supported."

The first bullet on page 3 would be changed to read, "The current state operated/managed focus of NELAP vs. federally mandated GLP programs."

The last two bullets were incorporated and changed to read, "Failure of NELAP to include the GLP regulated community in the initial federal advisory committee and in the initial drafting of the NELAC standards prior to 1995."

Third Party Assessors

Ms. Sandra Wroblewski and Mr. William Kavanagh agreed to rewrite the purpose and deliverables of the Third Party Assessors Working Group, addressing the criteria the states would use to select and evaluate assessors. These items will be discussed at the next meeting.

Other Business

A teleconference was subsequently scheduled for June 4, 1998 from 2 - 4:00 p.m.

Action Items
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Item No.	Action	Date Completed
1.	Mr. Hershey is to prepare a cover letter in which the concerns of the ELAB regarding the GLP Subcommittee Report are addressed.	
2.	Mr. Wynn John is to make the agreed upon changes to the GLP report and will provide an electronic copy with attachments to Ms. Jeanne Mourrain.	
3.	Ms. Sandra Wroblewski and Mr. William Kavanagh will rewrite the purpose of the Third Party Assessors Workgroup charter along with clarifying the other issues discussed during the meeting.	

List of Participants
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Name	Affiliation	Telephone Numbers
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